

**Standard Operating Procedure  
for  
Review and Response to Laboratory Corrective Action Plans**

Revision 6

Laboratory Services Division

Office of Environmental Assessment

Louisiana Department of Environmental Quality

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## Document Review and Revision Record

**Note: Actions older than 5 years may be removed from this record**

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## Table of Contents

1.0	Purpose.....	4
2.0	Scope.....	4
3.0	Evaluation of Corrective Action Plans.....	4
4.0	LELAP Response to Corrective Action Plans.....	5
5.0	Revised Corrective Action Plans.....	5
6.0	LELAP Response to Continuing Findings in Corrective Actions.....	5
7.0	Completion of Corrective Action.....	5
8.0	Policy Change Effective September 2, 2003.....	6

## APPENDIX

A	Template for LELAP Response to Corrective Action Plans All Approved.....	7
B	Template for LELAP Response to Initial Corrective Action Plans Incomplete or Not Approved.....	9
C	Template for LELAP Response to Revised Corrective Action Plans Incomplete or Not Approved.....	11
D	Template for Attestation of Compliance for Corrective Actions .....	13

## **STANDARD OPERATING PROCEDURES FOR REVIEW AND RESPONSE TO LABORATORY CORRECTIVE ACTIONS**

### **SOP #LELAP T-005**

#### **1.0 Purpose**

This standard operating procedure (SOP) establishes requirements to be followed by the Louisiana Environmental Laboratory Accreditation Program (LELAP) for the review and response to corrective action plans submitted by laboratories in response to findings identified during the assessment process.

#### **2.0 Scope**

This procedure shall be used by LELAP Assessors to review and respond to Corrective Action Plans (CAP) submitted by laboratories in response to findings identified during the assessment process.

#### **3.0 Evaluation of Corrective Action Plans**

The assigned LELAP Assessor shall review and evaluate all corrective action plans submitted by the laboratory within 30 working days of receipt of the documents. The assigned LELAP Assessor shall determine if the proposed CAP has adequately addressed each individual finding subject to final approval by the Program Supervisor or Laboratory Services Division (LSD) Administrator. The laboratory corrective action with respect to each finding shall be assigned to one of three categories by the LELAP Assessor:

**3.1 Approved – Corrective actions in this category must address the specific finding and must be sufficient to meet all existing requirements of the Louisiana Administrative Code (LAC) and/or 2003 NELAC Standard when successfully implemented and documented.**

**3.2 Incomplete – Corrective actions in this category are incomplete and shall require the laboratory to submit more information before a determination can be made as to whether the corrective action is satisfactory. The assigned LELAP Assessor shall identify the information that must be submitted to allow a final determination to be made.**

**3.3 Not Approved – Corrective actions in this category fail to adequately address the specific finding, or are insufficient to meet existing LAC requirements and or 2003 NELAC Standard. This category shall include but not be limited to those instances where no corrective action has been submitted for a specific finding.**

#### **4.0 LELAP Response to Corrective Action Plans**

The assigned LELAP Assessor shall submit a response to the laboratory's designated representative. The LELAP Assessor's response must include the evaluation of corrective actions specific to each finding listed in the Assessment Report. The response shall indicate where the laboratory is required to submit additional information, documentation, or corrective action for any finding. The following templates shall be used by LELAP Assessor to respond to corrective actions submitted by the laboratory:

- 4.1 Appendix A- Template for LELAP Response to Corrective Action Plans that are **All Approved**.
- 4.2 Appendix B- Template for LELAP Response to Initial Corrective Action Plans that are **Incomplete** or **Not Approved**.
- 4.3 Appendix C- Template for LELAP Response to Revised Corrective Action Plans that are **Incomplete** or **Not Approved**.

#### **5.0 Revised Corrective Action Plans**

The laboratory must submit a revised corrective action plan for any finding for which the previous corrective action has been found to be **Incomplete** or **Not Approved**. The laboratory must submit the revised corrective action plan no later than thirty (30) calendar days from date of receipt of the finding notice. The LELAP Assessor shall review and respond to these submissions by the same procedure as described in Sections 3.0-7.0 of this SOP.

#### **6.0 LELAP Response to Continuing Findings in Corrective Actions**

The accreditation process shall be subject to termination if the laboratory fails to submit proposed or completed corrective actions (CAP) within the time limits established by LAC 33:I.5107. If it is determined by LELAP that the laboratory has failed to correct known findings within the statutory timeframe, the laboratory's designated representative shall be notified by certified mail that its certification is suspended or revoked under LAC 33:I.5705.F.4.

#### **7.0 Completion of Corrective Action**

7.1 If the laboratory has failed to meet the statutory requirements of LAC, the LELAP Assessor shall notify the designated Laboratory representative in writing. The assigned LELAP Assessor shall initiate suspension or disaccreditation of the laboratory as established by LAC 33:I.5705 with the approval of the LELAP Supervisor or LSD Administrator.

7.2 If it has been determined by the LELAP Assessor that the laboratory has provided an acceptable corrective action plan or corrected all outstanding findings and provided satisfactory documentation of said correction, the LELAP Assessor shall notify the laboratory in writing that no further corrective action shall be required at this time and request that the laboratory sign the Attestation of Compliance for Corrective Action (Attached).

## **8.0 Policy Change Effective September 2, 2003**

As of September 2, 2003, LELAP has a new policy on Completed Corrective Action Documentation (CCAD).

**8.1 Purpose:** This policy provides the procedure for the corrective action process following an on-site assessment of a laboratory, to correct findings, or non-conformances, identified at the assessment. This procedure is designed to ensure corrective actions are approved in a timely manner and implementation of the corrective action is assessed.

**8.2 Scope:** This policy is for the Louisiana Environmental Laboratory Accreditation Program staff.

**8.3 Procedures:** Following an on-site assessment, the laboratory is issued an assessment report within 30 days. The assessment report lists the regulatory non-conformances identified by the assessor(s) during the assessment process. The laboratory is required to respond by issuing a corrective action plan (CAP) to LELAP within 30 days of the receipt of the assessment report. The laboratory is required to submit detailed corrective actions they will take to correct the finding. The CAP must identify who is responsible for the corrective action and implementation, the date implementation is complete, and what the lab will do to correct the finding and prevent its re-occurrence. The corrective action must be written so that LELAP staff understands all steps the lab will undertake to correct the identified problem. If the laboratory does not agree with the cited finding, the laboratory must address why the cited finding is in error and present supporting material where applicable. If any of the submitted corrective actions are not approved, the laboratory must submit a revised CAP within 30 days of receipt of the original CAP response addressing the assessors concerns. If the laboratory does not submit an acceptable corrective action on the second attempt, the accreditation process is terminated and the laboratory must re-apply. After the CAP is approved, the laboratory will be sent an Attestation of Compliance for Corrective Actions (Appendix C) it must sign and return to LELAP within 10 days upon receipt.

## **Appendix A**

### **Template for LELAP Response to Corrective Action Plans**

**All Approved**

**CERTIFIED MAIL# xxxx xxxx xxxx xxxx**  
**Return receipt requested**

Month day, year

**AI # xxxxxx**

**LELAP Lab ID #xxxxx**

Laboratory representative name  
Laboratory  
Address  
city, state zip

RE: Corrective Action Plan Response

Dear Laboratory representative name:

The Louisiana Department of Environmental Quality, Louisiana Environmental Laboratory Accreditation Program (LELAP, the Program) has reviewed your response to the quality system assessment findings of your laboratory. The onsite assessment was performed on month day, year. The formal assessment report was issued on month day, year. The corrective action plan (CAP) was received by the Program on month day, year.

Our review indicates that your CAP satisfactorily addresses the findings. The review is summarized in the table below, along with the date when each proposed corrective action was approved.

Finding Number	Response	Date Approved
1	Proposed Corrective Action Approved.	xx/xx/xxxx
2	Proposed Corrective Action Approved.	xx/xx/xxxx
3	Proposed Corrective Action Approved.	xx/xx/xxxx
4	Proposed Corrective Action Approved.	xx/xx/xxxx
5	Proposed Corrective Action Approved.	xx/xx/xxxx
6	Proposed Corrective Action Approved.	xx/xx/xxxx
7	Proposed Corrective Action Approved.	xx/xx/xxxx
8	Proposed Corrective Action Approved.	xx/xx/xxxx



LELAP requires that an attestation of compliance be completed prior to our final approval of these actions. Please sign and date the enclosed Attestation of Compliance form and return it to LELAP within ten (10) days of receipt of this notice.

Address all correspondence to the Office of Environmental Assessment, Louisiana Environmental Laboratory Accreditation Program, PO Box 4314, Baton Rouge, Louisiana, 70821-4314, Attention: LELAP Supervisor's Name.

If you have any questions, please contact Assessor name or me at (225) 219-9800.

Sincerely,

Name, Supervisor  
Louisiana Environmental Laboratory Accreditation Program

Supervisor's initial/ Assessor's initial (lower case)

Enclosure

## **Appendix B**

### **Template for LELAP Response to Initial Corrective Action Plans**

#### **Incomplete or Not Approved**

**CERTIFIED MAIL# xxxx xxxx xxxx xxxx**

**Return receipt requested**

Month day, year

**AI # xxxxx**

**LELAP Lab ID #xxxxxx**

Laboratory representative name

Laboratory

Address

city, state zip

RE: Corrective Action Plan Response

Dear Laboratory representative name:

The Louisiana Department of Environmental Quality, Louisiana Environmental Laboratory Accreditation Program (LELAP, the Program) staff has reviewed your response to the quality system findings of your laboratory. The laboratory assessment was performed on month days, year. The formal assessment report was issued on month day, year.

The comments submitted in the enclosed attachment address the corrective action plan (CAP) that was received by the Program on month day, year.

The review is summarized in the table below. You will note that x of y proposed corrective actions are approved. The remaining actions are not approved because they are incomplete or do not satisfactorily address all of the issues raised in the finding. Approved actions are noted with a date given for approval.

<b>Finding Number</b>	<b>Response</b>	<b>Date Approved</b>
1.	Proposed Corrective Action Not Approved.	
2.	Proposed Corrective Action Items Approved As Follows: A. The finding was withdrawn. B. Approved. C. Approved.	xx/xx/xxxx xx/xx/xxxx xx/xx/xxxx
3.	Proposed Corrective Action Items Approved As Follows: A. Approved. B. Approved. C. Approved.	xx/xx/xxxx xx/xx/xxxx xx/xx/xxxx
4.	Proposed Corrective Action Incomplete.	

You must submit a revised CAP to address the items that were not approved, within thirty days of your receipt of this notice. Your response must include a proposed date of completion for each finding and the name of the person responsible for completing the corrective action.

LELAP requires that an attestation of compliance be completed prior to our final approval of these actions. LELAP approval of proposed corrective actions does not absolve the laboratory of the responsibility to correct any existing findings (conditions that fail to satisfy the requirements of the Louisiana Administrative Code, Title 33, Part I, Subpart 3), including findings that may not have been identified during the audit process or the review of corrective action documents.

The Louisiana Administrative Code, §5107.B requires that all corrective actions must be completed and approved by LELAP no later than six months after your receipt of the assessment report. Requests for extension of deadlines must be submitted in writing, and must include a reasonable justification as to why an extension ought to be granted. Address all correspondence to the Office of Environmental Assessment, Louisiana Environmental Laboratory Accreditation Program, P.O. Box 4314, Baton Rouge, Louisiana, 70821-4314; Attention: LELAP Supervisor's Name.

If you have any questions, please contact Assessor's name or me at (225) 219-9800.

Sincerely,

Name, Supervisor  
Louisiana Environmental Laboratory Accreditation Program

Supervisor's initial: Assessor's initials (all lower case)

Enclosure

## **Appendix C**

### **Template for LELAP Response to Revised Corrective Action Plans**

#### **Incomplete or Not Approved**

**CERTIFIED MAIL# xxxx xxxx xxxx xxxx**  
**Return receipt requested**

Month day, year

**AI # xxxxx**

**LELAP Lab ID #xxxxx**

Laboratory representative name  
Laboratory  
Address  
City, State Zip

RE: Corrective Action Plan Response

Dear Laboratory representative name:

The Louisiana Department of Environmental Quality, Louisiana Environmental Laboratory Accreditation Program (LELAP, the Program) staff has reviewed your response to the quality system findings of your laboratory. The laboratory assessment was performed on month days, year. The formal assessment report was issued on month day, year.

The comments submitted in the enclosed attachment address the corrective action plan (CAP) that was received by the Program on month day, year.

The review is summarized in the table below. You will note that x of y proposed corrective actions are approved. The remaining actions are not approved because they are incomplete or do not satisfactorily address all of the issues raised in the finding. Approved actions are noted with a date given for approval.

Finding Number	Response	Date Approved
1.	Proposed Corrective Action Approved.	xx/xx/xxxx
2.	Proposed Corrective Action Items Approved As Follows: D. The finding was withdrawn. E. Approved. F. Approved.	xx/xx/xxxx xx/xx/xxxx xx/xx/xxxx
3.	Proposed Corrective Action Items Approved As Follows: D. Approved. E. Approved. F. Approved.	xx/xx/xxxx xx/xx/xxxx xx/xx/xxxx
4.	Proposed Corrective Action Incomplete.	

You must submit a revised CAP to address the items that were not approved, within thirty days of your receipt of this notice. Your response must include a proposed date of completion for each finding and the name of the person responsible for completing the corrective action.

LELAP requires that an attestation of compliance be completed prior to our final approval of these actions. LELAP approval of proposed corrective actions does not absolve the laboratory of the responsibility to correct any existing findings (conditions that fail to satisfy the requirements of the Louisiana Administrative Code, Title 33, Part I, Subpart 3), including findings that may not have been identified during the audit process or the review of corrective action documents.

The Louisiana Administrative Code, §5107.B requires that all corrective actions must be completed and approved by LELAP no later than six months after your receipt of the assessment report. Requests for extension of deadlines must be submitted in writing, and must include a reasonable justification as to why an extension ought to be granted. Address all correspondence to the Office of Environmental Assessment, Louisiana Environmental Laboratory Accreditation Program, P.O. Box 4314, Baton Rouge, Louisiana, 70821-4314; Attention: LELAP Supervisor's name.

If you have any questions, please contact Assessor's name or me at (225) 219-9800.

Sincerely,

Name, Supervisor  
Louisiana Environmental Laboratory Accreditation Program

Supervisor's initial: Assessor's initial (all lower case)

Enclosure

## **Appendix D**

### **Template for Attestation of Compliance for Corrective Actions**



**ATTESTATION OF COMPLIANCE  
FOR CORRECTIVE ACTIONS**

I, \_\_\_\_\_ of \_\_\_\_\_  
(Laboratory Director or QA Officer) (Laboratory Name)

understand and acknowledge that the laboratory is required to be continually in compliance with all the provisions and standards set forth in the Louisiana Administrative Code (LAC), Title 33, Chapter I, Subpart 3, "Laboratory Accreditation", which have been determined to be equivalent to the National Environmental Laboratory Accreditation Conference (NELAC) standards, and that the laboratory shall be subject to suspension, revocation, and denial of accreditation in accordance with the provisions of LAC 33:I.5705.

I further attest that all certified environmental analyses performed are done in accordance with the provisions and standards in LAC Title 33, Chapter I, Subpart 3, which have been determined to be equivalent to the NELAC standards. I hereby certify that the laboratory shall correct any findings or deviations identified during the assessment within six months from the date of receipt of the assessment report as required in LAC 33:I.5107.B and that failure to correct any findings or deviations identified during the assessment shall result in suspension or revocation of accreditation status in accordance with the provisions of LAC 33:I.5705.

I am authorized to sign this Attestation of Compliance on behalf of the applicant/owner and that there are no misrepresentations in the required Corrective Action Plan. The information, statements, facts, and representations given and made are true and correct, and I am aware that any misrepresentations or falsifications constitute grounds for suspension, revocation, or denial of accreditation.

\_\_\_\_\_  
(Signature, QA Officer or other designated responsible party)

\_\_\_\_\_  
(Printed Name of QA Officer)

\_\_\_\_\_  
(Printed Legal Name of Laboratory)

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(Signature, Technical Director)

\_\_\_\_\_  
(Printed Name, Technical Director)